MAR 07 2014

Wright Medical Technology, Inc.
5677 Airline Road Arlington, TN 38002
www.wmt.com

510(K) SUMMARY

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the WMT PRO-TOE® Hammertoe Fixation System line additions.

(a)(1). Submitted By:	Wright Medical Technology, Inc. 5677 Airline Road Arlington, TN 38002
Date:	January 21, 2014
Contact Person:	Val Myles Regulatory Affairs Specialist I Office - (901) 290-5162 Fax – (901) 867-4190
(a)(2). Proprietary Name:	PRO-TOE® Hammertoe Fixation System
Common Name:	Smooth or threaded metallic bone fixation fastener
Classification Name and Reference:	21 CFR 888.3040 – Class II
Device Product Code, Device Panel:	HWC- Orthopedic
(a)(3). Predicate Device:	K101165 – PRO-TOE™ VO Hammertoe Implant System K120645 – PRO-TOE™ Hammertoe Implant System K122959 – Trilliant Hammer Toe Implant K132895 – WMT Implantable K-Wires

(a)(4). Device Description

The PRO-TOE® Hammetoe Fixation System is composed of implants and instruments intended for use in the fixation or reconstruction of the lesser toes. The implants within the

PRO-TOE® Hammertoe System have proximal & distal fixation features and will be offered in multiple sizes. The implants are manufactured from stainless steel or titanium.
This submission seeks to add previously cleared WMT Implantable K-Wires to the system for use with cannulated implants, for which clearance is also sought in this submission. The WMT Implantable K-wires are offered in surgical grade stainless steel. A range of diameters and lengths are offered from the manufacturer and planning should be conducted prior to implantation to determine the best fit.

(a)(5). INTENDED USE

The PRO-TOE® Hammertoe Fixation Systems are indicated for the fixation of osteotomies and reconstruction of the lesser toes following correction procedures for hammertoe, claw toe, and mallet toe.

Cannulated Implants in the PRO-TOE® Hammertoe Fixation Systems can be used with K-wires for the delivery of implants or the temporary stabilization of outlying joints (e.g. MTP Joint).

The Implantable K-Wires are indicated for use in fixation of bone fractures, for bone reconstructions, and as guide pins for insertion of other implants. Additionally, Implantable K-Wires are indicated for the fixation of osteotomies and reconstruction of the lesser toe following correction procedures for hammertoe, claw toe, mallet toe, and metatarsophalangeal joint instability.

(a)(6). Technological Characteristics Comparison

The PRO-TOE® Hammertoe Fixation System and the legally marketed predicate devices have similar indications, dimensions and geometry, and are identical in material. The purpose of this submission is to add PRO-TOE® VO Cannulated and PRO-TOE® C2 implants to the PRO-TOE® Hammertoe System. Indications have been updated to include the additional indication for temporary stabilization of outlying joints (e.g. MTP joint), identical to that of the previously cleared WMT Implantable K-Wire.

(b)(1). Substantial Equivalence – Non-Clinical Evidence

Mathematical mechanical analysis related to static bend testing has shown that the subject implants do not present a new worst case.

(b)(2). Substantial Equivalence – Clinical Evidence

N/A

(b)(3). Substantial Equivalence – Conclusions

The design characteristics of the subject devices do not raise any new types of questions of safety or effectiveness. From the evidence submitted in this 510(k), the subject devices can be expected to perform at least as well as the predicate systems and are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 7, 2014

Wright Medical Technology, Inc.
Ms. Val Myles
Regulatory Affairs Specialist I
5677 Airline Road
Arlington, Tennessee 38002

Re: K140148
Trade/Device Name: PRO-TOE® Hammertoe Fixation System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: January 9, 2014
Received: January 22, 2014

Dear Ms. Myles:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

K140148

Device Name
PRO-TOE® Hammertoe Fixation System

Indications for Use *(Describe)*

The PRO-TOE® Hammertoe Fixation Systems are indicated for the fixation of osteotomies and reconstruction of the lesser toes following correction procedures for hammertoe, claw toe, and mallet toe.
Cannulated Implants in the PRO-TOE® Hammertoe Fixation Systems can be used with K-wires for the delivery of implants or the temporary stabilization of outlying joints (e.g. MTP Joint).
The Implantable K-Wires are indicated for use in fixation of bone fractures, for bone reconstructions, and as guide pins for insertion of other implants. Additionally, Implantable K-Wires are indicated for the fixation of osteotomies and reconstruction of the lesser toe following correction procedures for hammertoe, claw toe, mallet toe, and metatarsophalangeal joint instability.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Elizabeth L. Frank -S

Division of Orthopedic Devices

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